IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MMB Docket No. **1671-0281**

J & J Reference: **DEP5038USNP**

Confirmation No.: **2371**

Application of: **Keeven et al**

Group Art Unit: **3775**

Serial No.: **10/748,449**

Examiner: **Nicholas W. Woodall**

Filed: **December 30, 2003**

For: **Augments for Surgical Instruments**

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APPEAL BRIEF

Sir:

This is an appeal under 37 CFR § 41.31 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the rejection of the claims 24-43 of the above-identified patent application. These claims were indicated as rejected in an Office Action dated November 24, 2009. The $540.00 fee required under 37 CFR § 41.20(b) (2) has been submitted herewith along with the fee for a one month extension of time. The Director is hereby requested to please provide any extensions of time that may be necessary and charge any further fees that may be due to Account No. 13-0014, but not to include any payment of issue fees.

(1) REAL PARTY IN INTEREST

DePuy Products, Inc. of Warsaw, Indiana is the assignee of this patent application, and the real party in interest.

(2) RELATED APPEALS AND INTERFERENCES

Appeal 2008-0477 relates to this application. In that Appeal, which was decided on July 23, 2008, all rejections of claims 24-32 of the present application were reversed. Subsequently, the Examiner performed additional searches and issued various rejections based upon the new searches. A copy of the decision on the Appeal 2008-0477 is provided in the Appendix attached to this Brief.

(3) STATUS OF CLAIMS

Claims 17-43 are pending in the application.

Claims 1-16 have been cancelled.

Claims 17-23 have been withdrawn.

Claims 24-43 are rejected.

Claims 24-43 are being appealed, and are shown in the Appendix attached to this Appeal Brief.

(4) STATUS OF AMENDMENTS

The Appellants have filed no amendments after receipt of the November 24, 2009 Office Action (the "Office Action").

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Claims 24, 28, 37, and 41 are independent claims.

Claim 24

Claim 24 recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising (see, e.g., Appellants' specification at page 9, lines 9-19):

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), said positioning member including a first coupler (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), and (ii) a connector member having a first mating feature (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 4, reference number 56);

an augment (see, e.g., Appellants' specification at page 9, lines 9-10 FIGs. 7 and 8, reference number 70) having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74); and

a femoral resection guide (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 3, reference number 32) having a second mating feature that mates with said first mating feature of said instrument (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 3, reference number 23).

Claim 28

Claim 28 recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising (see, e.g., Appellants' specification at page 9, lines 9-19):

an instrument having a positioning member (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52) that includes a first coupler (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), said positioning member defining (i) a femur facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), (ii) a tibia facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), and (iii), a guide slot configured to receive an intramedullary pin (see, e.g., Appellants' specification at page 8, lines 14-17 and FIG. 4, reference number 54);

an augment (see, e.g., Appellants' specification at page 9, lines 9-10 FIGs. 7 and 8, reference number 70) having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74); and

an intramedually pin received within said guide slot of said positioning member of said instrument (see, e.g., Appellants' specification at page 8, lines 14-17).

Claim 37

Claim 37 recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising (see, e.g., Appellants' specification at page 9, lines 9-19):

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), said positioning member including a first coupler (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), and (ii) a connector member having a first mating feature (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 4, reference number 56);

an augment (see, e.g., Appellants' specification at page 9, lines 9-10 FIGs. 7 and 8, reference number 70) having a second coupler that cooperates with said first coupler to fix said augment to said positioning member (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74); and

a femoral resection guide (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 3, reference number 32) having a second mating feature that mates with said first mating feature of said instrument (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 3, reference number 23),

wherein said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein (see, e.g., Appellants' specification at page 10, lines 1-5 and FIG. 6, reference numbers 64 and 68), and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring (see, e.g., Appellants' specification at page 10, lines 1-5 and FIG. 8, reference number 74).

Claim 41

Claim 41 recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising (see, e.g., Appellants' specification at page 9, lines 9-19):

an instrument having a positioning member (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52) that includes a first coupler (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), said positioning member defining (i) a femur facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), (ii) a tibia facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), and (iii), a guide slot configured to receive an intramedullary pin (see, e.g., Appellants' specification at page 8, lines 14-17 and FIG. 4, reference number 54);

an augment (see, e.g., Appellants' specification at page 9, lines 9-10 FIGs. 7 and 8, reference number 70) having a second coupler that cooperates with said first coupler to fix said augment to said positioning member (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74); and

an intramedullary pin received within said guide slot of said positioning member of said instrument (see, e.g., Appellants' specification at page 8, lines 14-17),

wherein said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein (see, e.g., Appellants' specification at page 10, lines 1-5 and FIG. 6, reference numbers 64 and 68), and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring (see, e.g., Appellants' specification at page 10, lines 1-5 and FIG. 8, reference number 74).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 24-43 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter.

Claims 24, 33, and 34 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,721,104 of Kaufman et al. (hereinafter "Kaufman").

Claims 28 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,976,147 of LaSalle et al. (hereinafter "LaSalle").

Claims 25 and 26 stand rejected under 35 U.S.C. §103(a) as being obvious over Kaufman in view of U.S. Patent No. 5,931,838 of Vito (hereinafter "Vito").

Claim 27 stands rejected under 35 U.S.C. §103(a) as being obvious over Kaufman.

Claims 37-40 stand rejected under 35 U.S.C. §103(a) as being obvious over Kaufman in view of Vito.

Claims 29 and 30 stand rejected under 35 U.S.C. §103(a) as being obvious over LaSalle in view of U.S. Patent No. 5,639,113 of Goss (hereinafter "Goss").

Claim 31 stands rejected under 35 U.S.C. §103(a) as being obvious over LaSalle.

Claims 41-43 stand rejected under 35 U.S.C. §103(a) as being obvious over LaSalle in view of Goss.

(7) ARGUMENT

Claims 24-43 Are Not Non-Statutory Subject Matter

Claims 24-43 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 24-43 are directed to statutory subject matter. Therefore, the rejections should be reversed.

Specifically, the Examiner has alleged that the limitation of a positioning member that defines a "femur facing side and a tibia facing side" is a positive recitation of a part of a human body. (Office Action at page 2). While acknowledging that the terms (femur facing" and "tibia facing" are adjectives, the Examiner nonetheless contends that "the element having to include a femur facing side or a tibia facing side requires the presence of a femur or tibia for the sides to face and therefore includes the femur or tibia within the scope of the claims." (Office Action at page 2). The Examiner thus appears to acknowledge that the "tibia" and "femur" are *not* positively recited as alleged.

Contrary to the Examiner's apparent position, adjectival modifiers which inform a reader of the claims of the manner in which the device is to be used does not transform the nature of the thing claimed. Thus, the "positioning member" is not transformed into a living human being merely by providing a description of the manner in which the device is used. Rather, the provision of such descriptive language is a common practice used in claims to better inform the reader of structural characteristics o the claimed component in view of the manner in which the claimed device is used. Issued patents are replete with

such language. For example, U.S. Patent No. 6,645,215 of McGovern e al. includes claims drawn to a tibial template with a "tibia facing surface" (See, e.g., .S. Patent No. 6,645,215 at claim 3) and U.S. Patent No. 6,168,629 of Timoteo includes claims directed to a femoral component with a "femur facing surface." (See, e.g., .S. Patent No. 6,168,629 at claim 18). A similar approach is to use terms such as "bone facing surface." (See, e.g., U.S. Patent No. 7,547,308 of Bertagnoli, et al. at claim 17, which was examined by the present Examiner.)

As stated by the Federal Circuit, "claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." *In re Marosi,* 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), quoting *In re Okuzawa,* 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). The title of the Appellants' specification reads "AUGMENTS FOR SURGICAL INSTRUMENTS." The entire specification is directed to describing a system that can be used in orthopaedic procedures. (See, e.g. Appellants' specification at page 1, lines 3-5). The claims themselves state that the claims are for "A system for establishing a gap between a femur and a tibia." And the plain meaning of the limitations do not positively recite a tibia or a femur. Therefore, construing claims in a manner contrary to the express language of the claims, and contrary to the manner in which the invention is described, and contrary to the manner in which similar claims are commonly understood, so as to include a tibia or femur within the scope of the claims, is unreasonable.

Therefore, because any reasonable construction of claims 24-43 does not include a tibia or femur within the scope of the claims, claims 24-43 are directed to statutory subject matter. Therefore, the rejections should be reversed.

Claims 24, 33, and 34 Are Not Anticipated by Kaufman

Claims 24, 33, and 34 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kaufman. Kaufman does not disclose each element of the claims arranged in the manner required by the claims. Therefore, the rejections should be reversed.

Discussion re: Patentability of Claim 24

1. Claim 24

Claim 24 recites the following:

> A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
> an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;
> an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and
> a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument.

Claim 24 thus requires an augment.

2. The Examiner has Misconstrued the Claim

a. The Examiner's Construction.

Claim 24 requires an "augment." The Examiner has alleged that the component identified by reference number 5 of Kaufman is an augment. Kaufman discloses that the reference number 5 is a "femoral trial component." (Kaufman at column 4, lines 22-31

and FIG. 9B). As is commonly understood, a "trial" is a device which is used in place of a permanent prosthesis to ensure a proper anatomical fit will be achieved when a joint is reduced. (See, e.g., Kaufman at column 2, lines 56-61). The femoral trial component 5 of Kaufman is thus a component that can "mimic the manner in which the human knee functions after the components are implanted. (Kaufman at column 5, lines 65-68).

Accordingly, the Examiner has construed an "augment" to include a temporary joint component. While it is proper to give a claim element its broadest reasonable construction in examination proceedings, the Examiner's construction generalizes the word "augment" in a manner contrary to the plain meaning of the word and contrary to the manner in which the word is used in the Appellants' specification as discussed below. Therefore, the Examiner's construction is unreasonable.

b. A Femoral Trial is not an Augment

It is well established that the words of a claim must be given their plain meaning unless an applicant has provided a clear alternate definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Claim 24 clearly requires an "augment." *Merriam-Webster's Medical Dictionary. Retrieved May 21, 2010, from Dictionary.com website: http://dictionary.reference.com/browse/augment* defines "augment" in a verb form as "to increase in size, amount, degree, or severity." As a noun, an "augment" would thus be a thing that increases something else in size, amount, degree, or severity. Thus, an "augment" is not the primary component. Rather, an augment is a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into the place prepared for the primary component.

Thus, the Examiner's construction of an "augment" to be a *primary* component of a femoral trial is contrary to the plain meaning of the term "augment." In other words, the femoral trial 5 is not an augment because it does not modify the manner in which a primary component fits a prepared femur; it is the primary component that is placed on the prepared femur. Rather, an "augment" would be a component that could be used on an "as needed" basis for modifying the manner in which the femoral trial 5 fits onto the prepared femur.

c. The Specification Supports the Plain Meaning of "Augment"

Moreover, the plain meaning of the words in a claim must be determined in the context of the application. As stated by the Federal Circuit, "claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." *In re Marosi,* 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), quoting *In re Okuzawa,* 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original).

The definition of "augment" set forth above comports with the use of the word in the specification. By way of example, at page 4, lines 2-4, the Appellants' specification states "[t]here is a need, therefor, for an augment that can be readily used in the orthopaedic procedure to allow the guide instruments to properly emulate the natural anatomy of the instrumented joint." At page 5, lines 6-7, the Appellants' specification states "[t]he system further comprises an augment for filling the gap when coupled to the instrument." The Appellants' specification further states "an augment for filling the gap when coupled to the instrument." (Appellants' specification at page 6, lines 8-9). At

page 6, lines 19-12 the Appellants' specification notes that "[i]t is one object of the invention to provide an augment that can serve as a spacer or a shim as part of a system for establishing a prosthetic gap for a human joint." Furthermore, the Applicants' specification at page 9, lines 1-3 states "While the positioner 50 may be properly sized to achieve these results for some patients, the majority of the cases will require some augmentation for the surface alignment plate." Thus, the positioner 50 is a primary component of the system and the augment is used on an as-needed basis to help the positioner 50 to fit properly.

Therefore, the specification supports the plain meaning of the word "augment" in the context of a prosthesis system as a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place where the primary component is to be used.

d. Conclusion

Claim 24 clearly recites an "augment" and the Appellants' specification establishes that an "augment" is a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place where the primary component is to be used, a definition that is consistent with the plain meaning of the word "augment".

The Examiner has failed to identify any valid basis for expanding the meaning of the word "augment" beyond its plain meaning and beyond the manner in which the word is used in the specification or the claims. Therefore, the Examiner's construction of claim 24 is unreasonable.

3. Kaufman Does Not Disclose an Augment

When the word "augment" is properly construed, Kaufman does not disclose an augment with the characteristics required by claim 24. Specifically, the femoral trial component 5 is not an augment. Rather, it is a primary part of a trial that must be placed on a femur to provide insight into how a permanent prosthetic device will fit. (See, e.g., Kaufman at column 5, lines 65-68). Therefore, the femoral trial component 5 is not an augment.

4. Conclusion

The Federal Circuit has stated that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Kaufman does not disclose a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place where the primary component is to be used, Kaufman does not disclose each element of the Appellants' claim 24. Therefore, Kaufman does not anticipate Appellants' claim 24. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 24.

Discussion re: Patentability of Claim 33

1. Claim 33

Claim 33 recites the following:

The system of claim 24, wherein:

the tibia facing side is generally planar;
the augment includes an upper surface and a lower surface; and
the upper surface of the augment abuts the tibia facing side when the augment is fixed to the positioning member.

Claim 33 thus requires an augment that is located between the positioning member and the tibia when the system is being used on a tibia.

2. Argument of Claim 24 Applies

As an initial matter, claim 33 depends from claim 24 and includes all of the limitations of claim 24. The Examiner rejected claim 33 based upon the same art discussed above with respect to claim 24. Therefore, for the same reasons set forth above with respect to claim 24, claim 33 is patentable over the cited art.

3. Kaufman Does Not Disclose an Augment Arranged as Claimed

The Examiner has alleged that Kaufman teaches an augment that is located between the positioning member and the tibia when the system is being used on a tibia. (Office Action at page 3). The Examiner has mischaracterized Kaufman.

Specifically, the Examiner alleges that femoral trial component 5 of Kaufman is an augment that is located between the positioning member and the tibia when the system is being used on a tibia. (Office Action at page 2). As clearly depicted at FIG. 1 of Kaufman, however, when the device of Kaufman is being used, the femoral trial component 5 is positioned on the femur 6. Thus, the alleged positioning member is located between the tibia and the femoral trial component 5.

The Federal Circuit has stated:

> Because the Hallmark of anticipation is prior invention, the prior art reference --in order to anticipate under 35 U.S.C. § 102—must not only

> disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim."

Net Moneyin, Inc. v. Verisign, Inc., 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing, *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Since Kaufman does not disclose an augment that is located between the positioning member and the tibia when the system is being used on a tibia, Kaufman does not disclose each element of the Appellants' claim 33 arranged in the manner required by claim 33. Therefore, Kaufman does not anticipate Appellants' claim 33. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 33.

4. Conclusion

For any or all of the foregoing reasons, claim 33 is not anticipated by Kaufman. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 33.

Discussion Re: Patentability of Claim 34

Claim 34 depends from claim 33 and includes the limitations discussed above with respect to claim 33 and additional limitations. Therefore, for at least the same reasons set forth with respect to claim 33, claim 34 is patentable over Kaufman.

Claims 28 and 32 Are Not Anticipated by LaSalle

Claims 28 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by LaSalle. LaSalle does not disclose each element of the claims arranged in the manner required by the claims. Therefore, the rejections should be reversed.

Discussion re: Patentability of Claim 28

1. Claim 28

Claim 28 recites the following:

> A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
> an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;
> an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and
> an intramedullary pin received within said guide slot of said positioning member of said instrument.

Claim 28 thus requires a positioning member with a guide slot and an augment.

2. LaSalle Does Not Disclose an Instrument Arranged as Claimed

The Examiner has alleged that LaSalle teaches a positioning member that includes a guide slot. (Office Action at page 4). The Examiner has mischaracterized LaSalle.

Specifically, the Examiner alleges that tibial punch 18 of LaSalle is a positioning member. (Office Action at page 4). The Examiner has further alleged that the "bore in the middle of element 12 that receives element 16" is a guide slot. (Office Action at page 4). The Examiner has alleged, however, that the tibial punch 18 is a "positioning member" not the trial element 12. (Office Action at page 4). The tibial punch 18 does not include a guide slot that receives an intramedullary pin. Thus, the alleged guide slot is not positioned on the tibial punch 18 as required by the claim.

The Federal Circuit has stated:

> Because the Hallmark of anticipation is prior invention, the prior art reference --in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim."

Net Moneyin, Inc. v. Verisign, Inc., 88 USPQ2d 1751, 1758, (Fed. Cir. 2008), citing, *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Since LaSalle does not disclose a positioning member that includes a guide slot, LaSalle does not disclose each element of the Appellants' claim 28 arranged in the manner required by claim 28. Therefore, LaSalle does not anticipate Appellants' claim 28. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 28.

3. The Examiner has Misconstrued the Claim

Moreover, the Examiner's rejection is based upon an unreasonable construction of the claim.

a. The Examiner's Construction.

Claim 28 requires an "augment." The Examiner has alleged that the component identified by reference number 20 of LaSalle is an augment. LaSalle discloses that the reference number 20 is used to identify a "tibial bearing insert member." (LaSalle at column 3, line 67 through column 4, line 2 and FIG. 1). As is commonly understood by those of ordinary skill in the art, a "tibial bearing insert" is a device which is used in place of a permanent prosthesis to ensure a proper anatomical fit will be achieved when a joint is reduced. (See, e.g., LaSalle at column 7, lines 9-23). The tibial bearing insert member 20 of LaSalle is thus a component that includes articulation surfaces which is necessary to forming a joint with a femoral component. (See, e.g., LaSalle at column 7, lines 9-23 and 47-51).

Accordingly, the Examiner has construed an "augment" to include a temporary joint component that is a necessary part of a trial device. While it is proper to give a claim element its broadest reasonable construction in examination proceedings, the Examiner's construction generalizes the word "augment" in a manner contrary to the plain meaning of the word and contrary to the manner in which the word is used in the Appellants' specification, as discussed more fully below. Therefore, the Examiner's construction is unreasonable.

b. A Tibial Trial is not an Augment

It is well established that the words of a claim must be given their plain meaning unless an applicant has provided a clear alternate definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Claim 28 clearly requires an "augment." *Merriam-Webster's Medical Dictionary. Retrieved May 21, 2010, from Dictionary.com website: http://dictionary.reference.com/browse/augment* defines "augment" in a verb form as "to increase in size, amount, degree, or severity." As a noun, an "augment" would thus be a thing that increases a primary component in size, amount, degree, or severity. Thus, an "augment" is not a primary component of the thing with which it is used. Rather, an augment is a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place prepared for the primary component.

Thus, the Examiner's construction of an "augment" to be a *primary* component of a tibial trial is contrary to the plain meaning of the term "augment." In other words, the tibial bearing insert member 20 is not an augment because it does not modify the manner

in which a primary component fits into/onto the place prepared for the primary component. Rather, an "augment" would be a component that could be used on an "as needed" basis for modifying the manner in which the tibial bearing insert member 20 fits into the place prepared for the tibial bearing insert member 20.

c. The Specification Supports the Plain Meaning of "Augment"

Moreover, the plain meaning of the words in a claim must be determined in the context of the application. As stated by the Federal Circuit, "claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." *In re Marosi,* 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), quoting *In re Okuzawa,* 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original).

The definition of "augment" set forth above comports with the use of the word in the specification. By way of example, at page 4, lines 2-4, the Appellants' specification states "[t]here is a need, therefor, for an augment that can be readily used in the orthopaedic procedure to allow the guide instruments to properly emulate the natural anatomy of the instrumented joint." At page 5 lines 6-7 the Appellants' specification states "[t]he system further comprises an augment for filling the gap when coupled to the instrument." The Appellants' specification further states "an augment for filling the gap when coupled to the instrument." (Appellants' specification at page 6, lines 8-9). At page 6, lines 19-12 the Appellants' specification notes that "[i]t is one object of the invention to provide an augment that can serve as a spacer or a shim as part of a system for establishing a prosthetic gap for a human joint." Furthermore, the Applicants'

specification at page 9, lines 1-3 states "While the positioner 50 may be properly sized to achieve these results for some patients, the majority of the cases will require some augmentation for the surface alignment plate." The positioner 50 is thus a primary component while the augment is used on an as needed basis for modifying the manner in which the positioner 50 fits into/onto the place prepared for positioner 50.

Therefore, the specification supports the plain meaning of the word "augment" in the context of a prosthesis system as a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place prepared for the primary component.

d. Conclusion

Claim 28 clearly recites an "augment" and the Appellants' specification establishes that an "augment" is a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place prepared for the primary component, a definition that is consistent with the plain meaning of the word "augment".

The Examiner has failed to identify any valid basis for expanding the meaning of the word "augment" beyond its plain meaning and beyond the manner in which the word is used in the specification or the claims. Therefore, the Examiner's construction of claim 28 is unreasonable.

4. LaSalle Does Not Disclose an Augment

When the word "augment" is properly construed, Kaufman does not disclose an augment with the characteristics required by claim 28. Specifically, the tibial bearing insert member 20 is not an augment. Rather, it is a necessary part of a trial that provides insight into how a permanent prosthetic device will fit. (See, e.g., LaSalle at column 7, lines 9-23 and 47-51). Therefore, the tibial bearing insert member 20 is not an augment.

5. Conclusion

The Federal Circuit has stated that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since LaSalle does not disclose a component that is used on an "as needed" basis for modifying the manner in which a primary component fits into/onto the place prepared for the primary component, LaSalle does not disclose each element of the Appellants' claim 28. Therefore, LaSalle does not anticipate Appellants' claim 28. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 28.

Discussion Re: Patentability of Claim 32

Claim 32 depends from claim 28 and includes the limitations discussed above with respect to claim 28 and additional limitations. Therefore, for at least the same reasons set forth with respect to claim 28, claim 32 is patentable over LaSalle.

Claims 25 and 26 Are Not Obvious over Kaufman and Vito

Claims 25 and 26 stand rejected under 35 U.S.C. §103(a) as being obvious over Kaufman in view of Vito. The proposed modification does not arrive at the claimed invention and the Examiner has failed to provide a clear articulation of any reasons for obviousness. Therefore, the rejections should be reversed.

Discussion re: Patentability of Claim 25

1. Claim 25

Claim 25 recites the following:

> The system of claim 24, wherein:
> said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and
> said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 25 thus requires the augment to include a pin coupler.

2. Argument of Claim 24 Applies

As an initial matter, claim 25 depends from claim 24 and includes all of the limitations of claim 24. The Examiner rejected claim 25 based primarily upon Kaufman with further reference to Vito for the limitations added by claim 25. (Office Action at page 4). Even if Kaufman is modified in the manner suggested by the Examiner, such modification fails to correct the deficiencies of Kaufman with respect to the limitations of claim 24 discussed above regarding the patentability of claim 24. Therefore, for the reasons set forth above with respect to claim 24, the proposed modification does not arrive at the invention of claim 25.

3. A Clear Articulation for the Combination Has Not Been Provided

MPEP 2142 notes that "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." The Examiner has failed to clearly articulate the reasons that the invention of claim 25 is obvious.

Specifically, the Examiner has alleged that one of ordinary skill in the art would modify the femoral trial 5 of Kaufman to include a pin extending upwardly (as depicted in FIG. 1 of Kaufman) because "a mere reversal of the essential working parts of a device involves only routine skill in the art." (Office Action at page 5). As discussed above, the femoral trial 5 of Kaufmann is a trial femoral component that is used to perform a trial reduction. If the femoral trial 5 of Kaufman were modified to include pins extending outwardly (upwardly as depicted in FIG. 1 of Kaufman), the pins would contact the trial tibial component and prevent the joint from being reduced. The Examiner has failed to explain why one of ordinary skill in the art would modify the device of Kaufman in such a manner as to render it unsuitable for its intended purpose.

Because the Examiner has failed to provide a clear articulation explaining why one of ordinary skill in the art would modify a device that is provided with smooth surfaces to allow for a trial reduction to include pins extending from the smooth surface which would not allow a joint to be properly reduced, a *prima facie* case of obviousness has not been established with respect to claim 25.

3. Conclusion

For any or all of the foregoing reasons, claim 25 is not obvious over the proposed modification of Kaufman. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 25.

Discussion Re: Patentability of Claims 26

Claim 26 depends from claim 25 and includes the limitations discussed above with respect to claim 25 and additional limitations. Claim 26 was rejected based upon the same prior art and arguments discussed above with respect to claim 25. (Office Action at pages 4-5). Therefore, for at least the same reasons set forth with respect to claim 25, claim 26 is patentable over the proposed modification of Kaufman.

Claim 27 is Not Obvious over Kaufman

Claim 27 stands rejected under 35 U.S.C. §103(a) as being obvious over Kaufman. The proposed modification does not arrive at the claimed invention and the Examiner has failed to provide a clear articulation of any reasons for obviousness. Therefore, the rejections should be reversed.

Discussion re: Patentability of Claim 27

1. Claim 27

Claim 27 recites the following:

> The system of claim 24, wherein:
> said first coupler of said positioning member includes a bore, and
> said second coupler of said augment includes a pin that is received within said bore.

Claim 27 thus requires the augment to include a pin coupler.

2. Argument of Claim 24 Applies

As an initial matter, claim 27 depends from claim 24 and includes all of the limitations of claim 24. The Examiner rejected claim 27 based upon Kaufman with further reference to ordinary skill for the limitations added by claim 27. (Office Action at page 5). Even if Kaufman is modified in the manner suggested by the Examiner, such modification fails to correct the deficiencies of Kaufman with respect to the limitations of claim 24 discussed above regarding the patentability of claim 24. Therefore, for the reasons set forth above with respect to claim 24, the proposed modification does not arrive at the invention of claim 27.

3. A Clear Articulation for the Combination Has Not Been Provided

MPEP 2142 notes that "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." The Examiner has failed to clearly articulate the reasons that the invention of claim 27 is obvious.

Specifically, the Examiner has alleged that one of ordinary skill in the art would modify the femoral trial 5 of Kaufman to include a pin extending upwardly (as depicted in FIG. 1 of Kaufman) because "a mere reversal of the essential working parts of a device involves only routine skill in the art." (Office Action at page 5). As discussed above,

the femoral trial 5 of Kaufmann is a trial femoral component that is used to perform a trial reduction. If the femoral trial 5 of Kaufman were modified to include pins extending outwardly (upwardly as depicted in FIG. 1 of Kaufman), the pins would contact the trial tibial component and prevent the joint from being properly reduced. The Examiner has failed to explain why one of ordinary skill in the art would modify the device of Kaufman in such a manner as to render it unsuitable for its intended purpose.

Because the Examiner has failed to provide a clear articulation explaining why one of ordinary skill in the art would modify a device that is provided with smooth surfaces to allow for a trial reduction to include pins extending from the smooth surface which would not allow a joint to be properly reduced, a *prima facie* case of obviousness has not been established with respect to claim 27.

3. Conclusion

For any or all of the foregoing reasons, claim 27 is not obvious over the proposed modification of Kaufman. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 27.

Claims 37-40 Are Not Obvious over Kaufman and Vito

Claims 37-40 stand rejected under 35 U.S.C. §103(a) as being obvious over Kaufman in view of Vito. The proposed modification does not arrive at the claimed invention and the Examiner has failed to provide a clear articulation of any reasons for obviousness. Therefore, the rejections should be reversed.

Discussion re: Patentability of Claim 37

1. Claim 37

Claim 37 recites the following:

> A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
> an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;
> an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and
> a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument,
> wherein said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and
> said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 37 thus requires an augment with a pin coupler.

2. Argument of Claim 24 Applies

As an initial matter, claim 37 requires an "augment". For purposes of this Appeal, this is the same "augment" limitation discussed above with respect to the patentability of claim 24 over Kaufman. The Examiner rejected claim 37 based primarily on Kaufman with further reference to Vito for an O-ring. (Office Action at page 5). Therefore, for the reasons set forth above with respect to claim 24, the proposed modification of Kaufman fails to arrive at the invention of claim 37.

3. The Argument of Claim 25 Applies

Moreover, claim 37 requires the augment to include a pin coupler. For purposes of this Appeal, this is the same "pin coupler" limitation discussed above with respect to the patentability of claim 25 over the proposed modification of Kaufman. The Examiner rejected claim 37 based upon a proposed modification of Kaufman using the same

arguments that were used in support of the rejection of claim 25 over Kaufman and Vito. (Office Action at pages 4-6). Therefore, for the reasons set forth above with respect to claim 25, Examiner has failed to establish *prima facie* obviousness.

4. Conclusion

For any or all of the foregoing reasons, claim 37 is not obvious over the proposed modification of Kaufman with the device of Vito. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 37.

Discussion Re: Patentability of Claim 38

Claim 38 depends from claim 37 and includes the limitations discussed above with respect to claim 37 and additional limitations. Claim 38 was rejected based upon the same prior art and arguments discussed above with respect to claim 37. (Office Action at pages 6-7). Therefore, for at least the same reasons set forth with respect to claim 37, claim 38 is patentable over the proposed modification of Kaufman with the device of Vito.

Discussion re: Patentability of Claim 39

1. Claim 39

Claim 39 recites the following:

> The system of claim 37, wherein:
> the tibia facing side is generally planar;
> the augment includes an upper surface and a lower surface; and
> the upper surface of the augment abuts the tibia facing side when the augment is fixed to the positioning member.

Claim 39 thus requires the system to be configured in a specific arrangement when used to form a gap, specifically, the augment must be positioned between the instrument and the tibia.

2. Argument of Claim 37 Applies

As an initial matter, claim 39 depends from claim 37 and includes all of the limitations of claim 37. The Examiner rejected claim 39 based upon the same prior art and arguments discussed above with respect to the patentability of claim 37. (Office Action at page 5). Even if Kaufman is modified in the manner suggested by the Examiner, such modification fails to correct the deficiencies of Kaufman with respect to the limitations of claim 37 discussed above regarding the patentability of claim 37. Therefore, for the reasons set forth above with respect to claim 37, the proposed modification does not arrive at the invention of claim 39.

3. Prima Facie Obviousness Has Not Been Established

Moreover, claim 39 requires that the system be arranged such that when the system is positioned between a tibia and a femur, the augment is positioned between the instrument and the tibia. The Examiner has alleged that the femoral trial component 5 of Kaufman is an augment and that the drill means guide 2 of Kaufman is an instrument. (Office Action at page 6). When the device of Kaufman is assembled and positioned between a femur and a tibia, see, e.g., FIG. 1 of Kaufman, the femoral trial component 5 is positioned in the femur. (See also Kaufman at column 7, lines 67-68). Therefore, the alleged instrument is positioned between the augment and the tibia. An arrangement

wherein an instrument is positioned between an augment and a tibia is not the same as an arrangement wherein an augment is positioned between an instrument and a tibia.

Therefore, even if the system of Kaufman is modified in the manner proposed by the Examiner, such modification fails to arrive at the invention of claim 39.

4. Conclusion

For any or all of the foregoing reasons, claim 39 is not obvious over the proposed modification of Kaufman with Vito. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 39.

Discussion Re: Patentability of Claim 40

Claim 40 depends from claim 39 and includes the limitations discussed above with respect to claim 39 and additional limitations. Claim 40 was rejected based upon the same prior art and arguments discussed above with respect to claim 39 (Office Action at page 6). Therefore, for at least the same reasons set forth with respect to claim 39, claim 40 is patentable over the proposed modification of Kaufman with Vito.

Claims 29 and 30 Are Not Obvious over LaSalle and Goss

Claims 29 and 30 stand rejected under 35 U.S.C. §103(a) as being obvious over LaSalle in view of Goss. The proposed modification does not arrive at the claimed invention. Therefore, the rejections should be reversed.

Specifically, claims 29 and 30 depend, either directly or by way of an intermediate claim, from claim 28 and include all of the limitations of claim 28. The Examiner

rejected claims 29 and 30 based primarily upon LaSalle with further reference to Goss or ordinary skill for the limitations added by claims 29 and 30. (Office Action at page 7). Even if LaSalle is modified in the manner suggested by the Examiner, such modification fails to correct the deficiencies of LaSalle with respect to the limitations of claim 28 discussed above regarding the patentability of claim 28. Therefore, for the reasons set forth above with respect to claim 28, the proposed modification does not arrive at the invention of claims 29 and 30. Therefore, the rejections should be reversed.

Claim 31 is Not Obvious over LaSalle

Claim 31 stands rejected under 35 U.S.C. §103(a) as being obvious over LaSalle. The proposed modification does not arrive at the claimed invention. Therefore, the rejections should be reversed.

Specifically, claim 31 depends from claim 28 and includes all of the limitations of claim 28. The Examiner rejected claim 31 based primarily upon LaSalle with further reference to ordinary skill for the limitations added by claim 31. (Office Action at page 8). Even if LaSalle is modified in the manner suggested by the Examiner, such modification fails to correct the deficiencies of LaSalle with respect to the limitations of claim 28 discussed above regarding the patentability of claim 28. Therefore, for the reasons set forth above with respect to claim 28, the proposed modification does not arrive at the invention of claim 31. Therefore, the rejections should be reversed.

Claims 41-43 Are Not Obvious over LaSalle and Vito

Claims 41-43 stand rejected under 35 U.S.C. §103(a) as being obvious over LaSalle in view of Goss. The proposed modification does not arrive at the claimed invention. Therefore, the rejections should be reversed.

Discussion re: Patentability of Claim 41

1. Claim 41

Claim 41 recites the following:

> A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
> an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;
> an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and
> an intramedullary pin received within said guide slot of said positioning member of said instrument,
> wherein said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and
> said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 41 thus requires a positioning member with a guide slot and an augment.

2. Argument of Claim 28 Applies

As noted above, claim 41 requires a positioning member with a guide slot and an augment. For purposes of this Appeal, these are the same "guide slot" and "augment" limitations discussed above with respect to the patentability of claim 28. The Examiner rejected claim 41 based upon a proposed modification of LaSalle using the same arguments that were used in support of the rejection of claim 28 with respect to the guide slot and augment limitations. (Office Action at pages 8-9). Therefore, for the reasons set forth above with respect to claim 28, LaSalle does not teach, suggest or disclose the

"guide slot" and "augment" limitations of claim 41. Therefore, even if LaSalle is modified in the manner proposed by the Examiner, the proposed modification fails to arrive at the invention of claim 141. Thus, the Examiner has failed to establish *prima facie* obviousness.

3. Conclusion

For any or all of the foregoing reasons, claim 41 is not obvious over the proposed modification of LaSalle. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 41.

Discussion Re: Patentability of Claims 42-43

Claims 42-43 depend from claim 41 and include the limitations discussed above with respect to claim 41 and additional limitations. Claims 42-43 were rejected based upon the same prior art and arguments discussed above with respect to claim 41. (Office Action at page 9). Therefore, for at least the same reasons set forth with respect to claim 41, claims 42-43 are patentable over the proposed modification of LaSalle.

CONCLUSION

Claims 24-43 are directed to statutory subject matter, claims 24, 33, and 34 are not anticipated by Kaufman, claims 28 and 32 are not anticipated by LaSalle, claims 25 and 26 are not obvious over Kaufman in view of Vito, claim 27 is not obvious over Kaufman, claims 37-40 are not obvious over Kaufman in view of Vito, claims 29 and 30 are not obvious over LaSalle in view of Goss, claim 31 is not obvious over LaSalle, and

claims 41-43 are not obvious over LaSalle in view of Goss. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claims 24-43.

Respectfully submitted,

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(8) CLAIMS APPENDIX

Claim 24. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and

a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument.

Claim 25. The system of claim 24, wherein:

said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 26. The system of claim 25, wherein:

said bore defines an internal groove, and

said O-ring is positioned within said internal groove.

Claim 27. The system of claim 24, wherein:

said first coupler of said positioning member includes a bore, and

said second coupler of said augment includes a pin that is received within said bore.

Claim 28. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member abutting either said femur facing side or said tibia facing side; and

an intramedullary pin received within said guide slot of said positioning member of said instrument.

Claim 29. The system of claim 28, wherein:

said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 30. The system of claim 29, wherein:

said bore defines an internal groove, and

said O-ring is positioned within said internal groove.

Claim 31. The system of claim 28, wherein:

said first coupler of said positioning member includes a bore, and

said second coupler of said augment includes a pin that is received within said bore.

Claim 32. The system of claim 28, wherein said instrument further has a handle extending from said positioning member.

Claim 33. The system of claim 24, wherein:

the tibia facing side is generally planar;

the augment includes an upper surface and a lower surface; and

the upper surface of the augment abuts the tibia facing side when the augment is fixed to the positioning member.

Claim 34. The system of claim 33, wherein the lower surface is contoured.

Claim 35. The system of claim 28, wherein:

the guide slot extends from the femur facing side to the tibia facing side and opens to a front portion of the positioning member;

the augment includes an upper surface and a lower surface; and

an augment slot extends from the upper surface to the lower surface and opens to a front portion of the augment, the augment slot positioned such that when the augment is fixed to the positioning member (i) the upper surface of the augment abuts the tibia facing side and (ii) the augment slot is aligned with the guide slot.

Claim 36. The system of claim 28, wherein:

the tibia facing side is generally planar;

the augment includes an upper surface and a lower surface; and

the upper surface of the augment abuts the tibia facing side when the augment is fixed to the positioning member.

Claim 37. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and

a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument,

wherein said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 38. The system of claim 37, wherein:

said bore defines an internal groove, and

said O-ring is positioned within said internal groove.

Claim 39. The system of claim 37, wherein:

the tibia facing side is generally planar;

the augment includes an upper surface and a lower surface; and

the upper surface of the augment abuts the tibia facing side when the augment is fixed to the positioning member.

Claim 40. The system of claim 39, wherein the lower surface is contoured.

Claim 41. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and

an intramedullary pin received within said guide slot of said positioning member of said instrument,

wherein said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 42. The system of claim 41, wherein:

said bore defines an internal groove, and

said O-ring is positioned within said internal groove.

Claim 43. The system of claim 41, wherein said instrument further has a handle extending from said positioning member.

(9) EVIDENCE APPENDIX

(10) RELATED PROCEEDINGS APPENDIX

Appeal 2008-0477, decided on July 23, 2008. A copy of the decision on the Appeal 2008-0477 follows.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte
RICHARD D. KEEVEN and MARI TRUMAN

Appeal 2008-0477
Application 10/748,449
Technology Center 3700

Decided: July 23, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a system for establishing a gap at a knee joint. The Examiner has rejected the claims as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Claims 24-32 are on appeal. Claims 17-23 are also pending but have been withdrawn from consideration by the Examiner. We will focus on claims 24 and 28, which read as follows:

24. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and

a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument.

28. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and

an intramedually [sic] pin received within said guide slot of said positioning member of said instrument.

Claims 24, 27, 28, 31, and 32 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ritter (US 5,464,406, Nov. 7, 1995).

Claims 25, 26, 29, and 30 stand rejected under 35 U.S.C. § 103(a) as obvious over Ritter in view of Fraser (US 2002/0116009 A1, Aug. 22, 2002).

The Examiner contends that Ritter discloses

> a system for establishing a prosthetic gap between a femur and a tibia at a knee joint comprising an instrument having a positioning member 30, that defines a femur facing side and a

> tibia facing side, the positioning member includes a first coupler, 34, . . . and ha[s] a guide slot, 32, . . . and a connector member, 38, having a first mating feature, an augment, 96, having a second coupler, 86, . . . that cooperates with the first coupler to fix the augment to the positioning member, and a femoral resection guide, 70, having a second mating feature . . . that mates with the first mating feature of the instrument.

(Ans. 3-4.) The Examiner also contends that a "review of figure 8 of the Ritter et al. reference clearly discloses that the flange, i.e., 34, couples/fixes the augment, i.e., 96, to the positioning member, i.e., 30, which is located in the intramedullary canal of the femur, i.e., 27" (*id.* at 5). In addition, the Examiner contends that Ritter "discloses an intramedullary pin, i.e., 182, which is received in the guide slot, i.e., 32, of the positioning member, i.e., 30, of the instrument" (*id.* at 6).

Appellants contend that the Examiner has not set forth a prima facie case that Ritter anticipates claims 24 and 28 (App. Br.* 8-11 & 15-17; Reply Br. 2-11).

FINDINGS OF FACT

1. Claim 24 requires an instrument having both a positioning member having a first coupler and a connector member having a first mating feature.

2. Claim 24 additionally requires an augment having a second coupler that cooperates with the first coupler to fix the augment to the positioning member.

3. Claim 28 requires an instrument having a guide slot and an intramedullary pin received within the guide slot.

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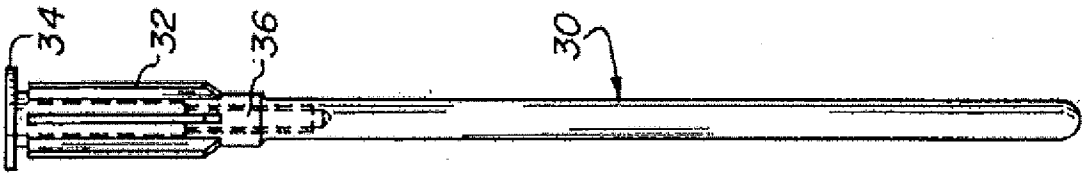
* February 2007 Amended Appeal Brief.

4. Ritter discloses a "set of surgical instruments **28** compris[ing] an intramedullary rod **30**" (Ritter, col. 3, ll. 63-64).

5. A portion of Ritter Figure 2 is reproduced below:



This portion of Figure 2 depicts an intramedullary rod 30 (*id.* at col. 3, ll. 57-66).

6. Ritter discloses that the "intramedullary rod **30** . . . comprises a plurality of flutes **32** which are used to prevent rotation of the intramedullary rod **30** when the intramedullary rod **30** is located in the femur **27**" (*id.* at col. 3, l. 66, to col. 4, l. 2).

7. Ritter discloses that "the intramedullary rod **30** also includes a flange portion **34** which is used when impacting the intramedullary rod **30** into the femur **27**" (*id.* at col. 4, ll. 2-5).

8. Ritter discloses that the "intramedullary rod **30** also comprises a blind bore **36** as well as a hex portion **38**. . . . The hex portion **38** is used for attaching other instrumentation to intramedullary rod **30**." (*Id.* at col. 4, ll. 5-10.)

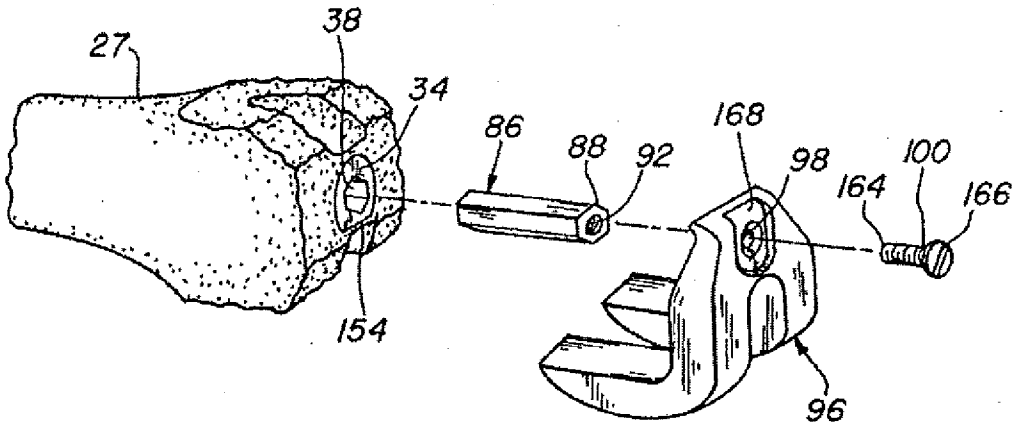
9. Ritter also discloses an angled support member 86 for attaching instruments to the intramedullary rod 30 (*id.* at col. 5, ll. 18-21).

10. Ritter states that the "exterior of the angled support member **86** is hexed shaped so as to be operable to be inserted into the hex portion **38** of intramedullary rod **30**" (*id.* at col. 5, ll. 20-24).

11. Ritter also discloses that the set of surgical instruments includes a femoral provisional 96 (*id.* at col. 5, ll. 47-48).

12. Ritter states that the "femoral provisional **96** comprises a passage **98** which is used for attaching the femoral provisional **96** to angled support member **86**" (*id.* at col. 5, ll. 50-53).

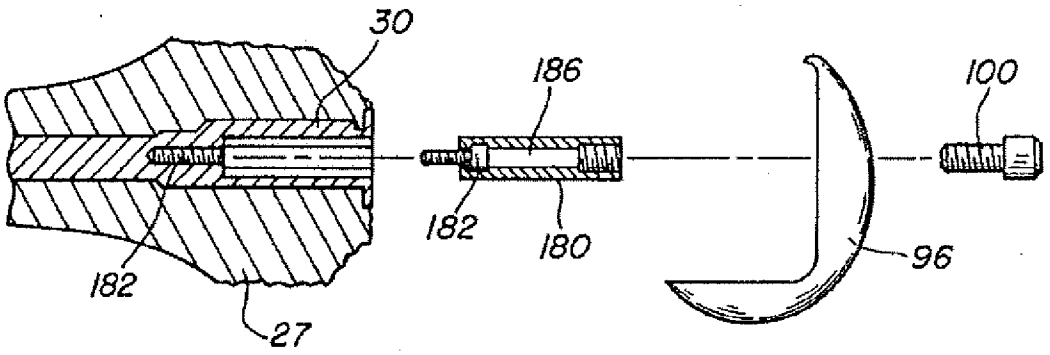
13. Ritter Figure 8 is reproduced below:



This figure depicts an exploded view "showing the use of the femoral provisional" (*id.* at col. 2, ll. 55-57). As depicted in Figure 8, the angled support member 86, which is attached to femoral provisional 96, is inserted into hex portion 38 of the intramedullary rod (*see also* Ritter, col. 9, ll. 16-19). Figure 8 also shows that flange 34 surrounds hex portion 38.

14. Ritter Figures 9 and 10 depict a gap between femur 27 and femoral provisional 96. This indicates that the femoral provisional is not in direct contact with flange 34, which, as depicted in Figure 8 above, is adjacent to femur 27.

15. Ritter Figure 20 is reproduced below:



This figure depicts an embodiment where the "angled support member **180** ha[s] an internal threaded member in the form of a screw **182** . . . to threadably engage a threaded portion **184** of the blind bore **36** so as to secure the angled support member **180** to the blind bore **36**" (*id.* at col. 11, ll. 2-8).

16. In Ritter Figure 20, screw 182 is not received within flutes 32, which, as depicted in Figure 2, are on the outside of intramedullary rod 30, not in blind bore 36.

ANALYSIS

With regard to claim 24, Appellants argue that Ritter's flange does not fix anything to the intramedullary rod (App. Br. 10). In particular, Appellants argue that Ritter's

> angled support 86 is inserted into the bore 36 of the intramedullary rod 30 "until the angled support member 86

> contacts the head 62 of the screw 58." (Ritter at column 9, lines 16-19, see also FIG. 11). Therefore, Ritter only discloses contact between the angled support 86 and both the hex portion of the bore 36 and the head 62 of the screw 58. Ritter never teaches, discloses or suggests that the flange 34 ever contacts the provisional femoral 96 or the angled support 86.

(App. Br. 11.) "Accordingly, because the flange 34 of Ritter plays no role in 'fixing' the provisional femoral 96 to the intramedullary rod 30, Ritter does not disclose a first coupler on the positioning member that performs the function required by the coupler in claim 24" (*id.*).

We agree with Appellants that the Examiner has not set forth a prima facie case that Ritter anticipates claim 24. The Examiner identifies intramedullary rod 30 as the instrument and flange 34 as the first coupler (Ans. 3). The Examiner also identifies femoral provisional 96 as the augment and angled support member 86 as the second coupler (*id.*). Ritter Figure 8 depicts inserting angled support member 86 into hex portion 38 of the intramedullary rod (Finding of Fact (FF) 13). In addition, Ritter Figure 8 shows that flange 34 surrounds hex portion 38 (FF 13). However, we do not agree with the Examiner (Ans. 5) that this Figure demonstrates that flange 34 fixes the femoral provisional to the intramedullary rod. Instead, this Figure demonstrates that hex portion 38, which the Examiner has identified as the first mating feature not the first coupler (Ans. 3), cooperates with the angled support member to attach the femoral provisional to the intramedullary rod (FF 8-14). Thus, we agree with Appellants that the Examiner has not set forth a prima facie case that angled support member 86 cooperates with flange 34 to fix the femoral provisional to the

intramedullary rod. We therefore reverse the anticipation rejection of claim 24 and of claim 27, which depends from claim 24.

With regard to claim 28, Appellants argue that the "flutes of Ritter fail to perform the recited function of receiving an intramedullary pin" (App. Br. 16). In particular, Appellants argue that screw 182 "is positioned within the blind bore 36. Accordingly, when the device of Ritter is assembled with the screw 182 within the blind bore 36, the screw 182 does not interact with the flutes 32 in any fashion." (Reply Br. 6.)

We agree with Appellants that the Examiner has not set forth a prima facie case that Ritter anticipates claim 28. The Examiner identifies flutes 32 as the guide slot and screw 182 as the intramedullary pin (Ans. 3 & 6). The Examiner has not shown that Ritter describes a device in which screw 182 is received by flutes 32 (FF 5-6 & 15-16). Thus, we agree with Appellants that the Examiner has not set forth a prima facie case that Ritter describes an intramedullary pin received within a guide slot, as recited in claim 28. We therefore reverse the anticipation rejection of claim 28 and of claims 31 and 32, which depend from claim 28.

With regard to the obviousness rejection of claims 25, 26, 29, and 30, each of these claims depends from either claim 24 or claim 28. We have already concluded that the Examiner has not set forth a prima facie case that Ritter anticipates claims 24 or 28. In addition, the Examiner has not set forth sufficient basis to conclude that claims 24 and 28 would have been obvious over Ritter. The Examiner relies on Fraser for limitations recited in dependent claims, and has not pointed to any disclosure in this reference that would make up for the deficiencies discussed above. Thus, we conclude that

the Examiner has not set forth a prima facie case that claims 25, 26, 29, and 30 would have been obvious. We therefore reverse the obviousness rejection of these claims.

CONCLUSION

The Examiner has not shown that the claims were anticipated by or would have been obvious to a person of ordinary skill in the art based on the applied references. We therefore reverse the anticipation rejection of claims 24, 27, 28, 31, and 32 and the obviousness rejection of claims 25, 26, 29, and 30.

REVERSED

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